

## REMARKS

On 5 December 2006 Applicants submitted an Amendment and a Notice of Appeal. The Examiner subsequently indicated in the Advisory Action of 23 January 2007 that the 5 December 2006 amendment has been entered for the purpose of appeal. Applicant requests that the 5 December 2006 amendment be entered into the record, and that the Examiner further enter the Amendments above accompanying the instant RCE.

Accordingly, claims 73 and 74 are currently amended. Claims 59-74 and 77-79 are pending in this Application.

It is respectfully submitted that the present amendments present no new matter and place this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### **I. The Objections to Claims 69, 70, 72 and 75-77 under 37 CFR 1.75(c).**

It is respectfully submitted that dependent claims 69, 72 and 77 provide additional limitation in that these claims include substitutions with greater specificity. Thus, the dependent claims are narrower than the claim from which they depend. Reconsideration is urged.

Claims 73 and 74 are currently amended. Reconsideration is urged.

### **II. The Objections to Claims 69, 70, 72 and 75-77.**

The Applicants respectfully disagree with the Examiner that claims 69, 70, 72 and 77 recite positions for substitution not present in claim 59. Applicants respectfully ask the Examiner to reconsider and please identify any missing positions with specificity.

### **III. The Rejection of Claims 59-74 and 77-79 for Nonstatutory Obviousness-type Double Patenting**

Claims 59-74 and 77-79 stand rejected on the grounds of non-statutory double patenting as being unpatentable over claims 1, 2, and 7-9 of U.S. Patent No 5,362,414 to Outtrup et al. (hereinafter simply referred to as "Outtrup"). In the advisory action dated 23 January 2007, the Examiner has indicated that claims 1, 2 and 7 of Outtrup describe the proteases and compositions of claims 59-74 and 77-79. Thus the Examiner has essentially indicated that the pending claims are not patentably distinct from Outtrup because the more broadly-stated patent claims embrace the subject matter of claims 59-74 and 77-79 herein. This rejection is respectfully traversed.

Obviousness double patenting is a judicially created doctrine grounded in public policy rather than statute. *In re Longi*, 225 U.S.P.Q. 645, 648 (Fed. Cir. 1985). The purpose of this rejection is to prevent the extension of the term of a patent by prohibiting the issuance of the claims in a second patent not patentably distinct from the claims of the first patent. *Id.* The Federal Circuit has indicated that the issue in determining whether an obviousness double patenting rejection is appropriate is "whether the claimed invention in the application for the second patent would have been obvious from the subject matter of the claims in the first patent, in light of the prior art." *Id.* Generally, a "one-way" test has been applied to determine obviousness- type double patenting. Under that test, the examiner asks whether the application claims are obvious over the patent claims. *In Re Berg*, 46 U.S.P.Q.2d 1226 (Fed. Cir. 1998).

The present disclosure relates to a variant TY145 like subtilase including an alteration at one or more specified positions; wherein the variant has protease activity and has an amino acid sequence which is at least 90% homologous to SEQ ID NO: 1 and each position corresponds to a position of the amino acid sequence shown in SEQ ID NO: 1. Claim 59 requires an alteration at position 171. Claim 79 requires an alteration at position 116. These alterations are not taught by Outtrup thus are not obvious as explained below.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Outtrup relates to detergent proteases derived from a strain of *Bacillus* sp. TY 145. Moreover, Outtrup is directed towards a process for the preparation of the protease, the use of the protease enzyme, and detergent composition including the protease of Outtrup. With respect to independent claim 59, Outtrup is devoid of any suggestion to employ a variant TY145 like subtilase including an alteration at position 171 as required by independent claim 59. Moreover, Outtrup does not specifically teach the claimed combination of an alteration at position 171 and at least one of the other specified position, wherein the variant has protease activity and has an amino acid sequence which is at least 90% homologous to SEQ ID NO: 1

and each position corresponds to a position of the amino acid sequence shown in SEQ ID NO: 1 as required by independent claim 59.

If one of skill in the art were to refer to the teachings Outtrup the result might just as likely be to use some other variant devoid of an alteration at position 171. Thus, one is just as likely to arrive at some other variant composition than the Applicant's claimed invention. Accordingly, nothing in Outtrup teaches, suggests or motivates one skilled in the art to modify position 171 in combination with the other specified positions required by independent claim 59.

Because Outtrup does not either alone or in combination with any reference teach or suggest a variant TY145 like subtilase including an alteration at position 171, and at least one of the other specified position, wherein the variant has protease activity and has an amino acid sequence which is at least 90% homologous to SEQ ID NO: 1 and each position corresponds to a position of the amino acid sequence shown in SEQ ID NO: 1, independent claim 59 (or any claims that depends therefrom) is not obvious. Accordingly withdrawal of the rejection of claims 59-78 is deemed appropriate and is respectfully requested.

With respect to independent claim 79, Outtrup is devoid of any suggestion to employ a variant TY145 like subtilase including an alteration the specified positions required by independent claim 79. Moreover, Outtrup does not specifically teach the claimed combination of an alteration at one or more positions selected from the group consisting of:

1, 2, 3, 4, 5, 6, 7, 16, 17, 18, 19, 20, 21, 22, 23, 31, 35, 36, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 79, 80, 81, 84, 85, 86, 87, 88, 89, 90, 91, 92, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 193, 198, 199, 200, 201, 202, 204, 207, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 239, 240, 241, 242, 243, 247, 248, 249, 250, 251, 252, 254, 265, 266, 268, 269, 270, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306 and 307; and  
an alteration comprising D116H,K,R,

wherein the variant has protease activity and has an amino acid sequence which is at least 90% homologous to SEQ ID NO: 1 and each position corresponds to a position of the amino acid sequence shown in SEQ ID NO: 1.

If one of skill in the art were to refer to the teachings Outtrup the result might just as likely be to use some other variant devoid of the alterations listed above. Thus, one is just as likely to arrive at some other variant composition than the Applicant's claimed invention. Accordingly, nothing in Outtrup teaches, suggests or motivates one skilled in the art to modify the positions above as required by independent claim 79.

Because Outtrup does not either alone or in combination with any reference teach or suggest a variant TY145 like subtilase including the claimed alterations, including an alteration at D116H,K,R, wherein the variant has protease activity and has an amino acid sequence which is at least 90% homologous to SEQ ID NO: 1 and each position corresponds to a position of the amino acid sequence shown in SEQ ID NO: 1, independent claim 79 is not obvious. Accordingly withdrawal of the rejection of claim 79 is deemed appropriate and is respectfully requested.

#### **IV. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone at (212) 840-0097 (x14) if there are any questions concerning this amendment or application.

Respectfully submitted,

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/Michael W. Krenicky Reg. # 45,411/  
Michael Krenicky, Reg. No. 45,411  
Novozymes North America, Inc.  
500 Fifth Avenue, Suite 1600  
New York, NY 10110  
(212) 840-0097 X 14